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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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08/971,172    11/14/97    GOODMAN

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HM22/0327

EXAMINER

TURNER, S

ART UNIT

PAPER NUMBER

1647

DATE MAILED:

03/27/01

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.

08/971,172

Applicant(s)

Goodman

Examiner

Sharon Turner

Group Art Unit

1647



☒ Responsive to communication(s) filed on Sep 7, 2000

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claims

☒ Claim(s) 68-1109 is/are pending in the application.

Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.

☐ Claim(s) \_\_\_\_\_ is/are allowed.

☒ Claim(s) 68-1109 is/are rejected.

☐ Claim(s) \_\_\_\_\_ is/are objected to.

☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some\* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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### **Response to Amendment**

1. The declaration and amendment filed 9-7-00 and the response to the notice to comply with the Sequence Rules filed 1-9-01 have been entered into the record and have been fully considered.
2. Claims 10-67 are canceled. Claims 68-119 are pending.
3. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

### **Rejections**

#### ***Specification***

4. The amendment filed 9-7-00 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which does not appear to be supported by the original disclosure is as follows: At p. 4, lines 26-27, insertion of "residues 1-937", lines 27-28, "residues 1-942", line 28, "residues 1-284".

Applicant is required to cancel the new matter in the reply to this Office action.

#### ***Claim Rejections - 35 USC § 101***

5. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

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6. Claims 68-119 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility.

The specification discloses the amino acid and nucleic acid sequence of related Robo1 and Robo2 polypeptides. The specification further discloses that the claimed polypeptides can regulate cell, especially nerve cell function and morphology and that the polypeptides may be either made recombinantly using the disclosed polynucleotide sequence. Also disclosed are isolated hybridization probes and primers capable of specific hybridization, methods of making and using the compositions in diagnosis, therapy and for making reagents, see in particular p. 3 lines 3-16. However, the specification appears to merely disclose a research plan for performing further experimentation aimed at the discovery of such real-world uses for the claimed sequences. For example, the specification fails to disclose any specific and substantial, credible regulation of cell function, change in morphology, disease to be diagnosed or therapy which is achieved. Thus the disclosed utilities appear to merely constitute research reagents which rely on the inherent properties of any nucleic acid to hybridize and encode. Further no evidence or art of record presents a well established utility for the claimed nucleotides. Thus, for the aforementioned reasons the claimed nucleic acids lack a defined specific and substantial, credible utility or a well established utility.

***Claim Rejections - 35 USC § 112***

7. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any

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person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 68-119 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial, credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

9. Claims 81, 92, 100, 102-104, 113-114, rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection. The isolated residues which specifically do not appear to be supported by the specification as originally filed are as follows; residues 1-942 of SEQ ID NO:4, residues 1-937 of SEQ ID NO:6, residues 1081-95 of SEQ ID NO:8, residues 68-259 of SEQ ID NO:8, residues 82-185 of SEQ ID NO:10, and residues 1-284 of SEQ ID NO:10.

***Claim Rejections - 35 USC § 102***

10. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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11. Claims 88-90 are rejected under 35 U.S.C. 102(a) as being anticipated by Sptrembl-11 sequence O01632 (of record) and Genbank Accession No. U88183.

As previously set forth for alignment O01632 and reference Wilson et al., of record corresponding to U88183, U88183 teaches isolated polynucleotide encoding residues 424-1297 of SEQ ID NO:6 and thus anticipates claims 88-90 drawn to nucleic acids encoding 12, 32 and 64 consecutive residues of SEQ ID NO:6.

Applicants argue that the examiner appears to rely on a sequence deposit designated O01632 which corresponds to U88183 reportedly released on April 21, 1997 and submit a declaration under 37 CFR 1.131 stating that applicants sequenced their U88183 clone prior to April 1997.

Applicants declaration under 37 CFR 1.131 submitted 2-16-00 has been fully considered but is not persuasive because the relevant date of the U88183 sequences is 2-14-1997 as created by Genbank.

12. Claims 108-110 are rejected under 35 U.S.C. 102(a) as being anticipated by Genbank Accession No:Z95705, May 25, 1997 which shares 100% identity with SEQ ID NO:7, residues 1016-1891 and 1901-4956 over its entire length. Thus Z95705 anticipates the nucleic acids as claimed.

Applicants argue that the supplemental 1.131 declaration exhibiting SEQ ID NO:7 and isolated in <sup>4.24.97</sup> 1996 obviates the rejection.

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Applicants arguments filed 9-7-00 have been fully considered but are not persuasive as the 3' end of the Word document appears to differ from SEQ ID NO:7 in particular beginning at p.2, line 38 of the sequence.

13. Claims 94-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Genbank Accession No:O01632 (U88183) as applied to claims 88-90 and further in view of Sambrook et al, Molecular Cloning, Cold Spring Harbor Labs, 1989, 16.1-16.16.

As set forth above Genbank Accession No:U88183 teaches consecutive residues of SEQ ID NO:6. However, Genbank Accession No:U88183 does not teach the nucleic acids in a vector and host cell for the production of polypeptides as claimed in claims 94-95. The relative skill in the art is reflected by Sambrook et al which teach the expression of cloned DNA in mammalian cells using vector nucleic acids. Such vector and host cell materials were readily available, at the time of the invention. The skilled artisan is well apprised of such cloning techniques widely known in the art. It would have been prima facie obvious for one of skill in the art knowing the DNA of U88183, to clone the DNA molecule into a vector and host cell using the techniques of Sambrook et al for the replication of the claimed nucleic acids, expression of the polypeptides, and subsequences thereof. One would have been motivated to clone such nucleic acids into a polypeptide expression vector in order to study the protein produced thereby from the cells. Further, one would have expected success based on the high skill in the art, the teachings of Sambrook et al and the publicly availability of numerous cell lines capable of expression. The

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knowledge of the appropriate DNA sequence taught by U88183 in the prior art thus renders the claimed nucleic acids, vectors, host cells and method of producing the polypeptides obvious.

**Status of Claims**

**Conclusion**

14. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached at (703) 308-4623.

Sharon L. Turner, Ph.D.  
March 26, 2001

**CHRISTINE J. SAOUD  
PRIMARY EXAMINER**

*Christine J. Saoud*